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Third day of August 2000

K Ward

KAY WARD
TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

COLOCARE HOLDINGS PTY LIMITED

PROVISIONAL SPECIFICATION

Invention Title:

Stoma care device and method

The invention is described in the following statement:

change the wafer and bag frequently seriously affects a patient's quality of life.

With the traditional methods, it has also been found that a certain amount of more fluid waste material has a tendency to collect at the entrance to the bag and thus removal of the bag may cause leakage of this material.

Moreover, the need to use the traditional wafer and collection bag devices imposes several problems for the ostomate, including restrictions to lifestyle (eg. poor utility, inconvenience, and need for dietary changes), psychological issues (eg. sexuality and poor self esteem) and an increased risk of herniation.

The introduction of irrigating liquid into the large intestine through the stoma can be used to stimulate faecal evacuation. One example of a device for introducing irrigating fluid that relies upon a gravity feed of the fluid into the intestine is described in US 4804373. While describing a means of introducing an irrigating fluid, the device does not address many of the problems of the traditional wafer and bag systems.

A means of collecting waste material from the bowel of a patient is described in International Application No. PCT/AU97/00145. This application describes the use of a suction pump to aid evacuation of waste material from the bowel in place of the traditional adhesive bag method.

The present invention aims to provide a still further means of evacuating waste material which overcomes the problems associated with the traditional bag and wafer devices, improves the efficacy of traditional irrigation systems and suction systems such as described above.

Summary of the Invention

According to a first aspect, the present invention consists in a device for evacuating waste product through an orifice in a mammalian body, the device including a chamber having an inlet and an outlet, the inlet being able to be brought into abutment with the body about the orifice and the outlet being connectable to a suction means, and an irrigating means for introducing an irrigating fluid into the orifice, the irrigating means having a free end that is movable relative to the chamber between at least a first position outside the orifice and a second position at least partially within the orifice.

According to a second aspect, the present invention consists in a system for evacuating waste product through an orifice in a mammalian

respectively. An O-ring can be located adjacent the screw thread between the skirt portion and the chamber to prevent waste product escaping from the chamber between the skirt portion and the wall of the chamber.

The second end can be formed from a material different to that of the chamber. As an example only, the second end can be formed from a polymeric material, such as nylon.

The chamber preferably has a further orifice formed therein to allow pressure equalisation between the interior and exterior of the chamber. The further orifice can be formed in a wall of the chamber or in the second end of the chamber. The further orifice can have an open-ended tube connected thereto. As a safety feature, and for ease of use, the further orifice is preferably adapted to be sealable by a finger of the user but could be closable or openable by other means. For example, the further orifice could be sealed by a pressure release valve or electronically actuated valve. Such a valve would vent the chamber should the pressure level within the chamber fall below some pre-set limit. The use of the further orifice in the chamber is described in more detail below.

The chamber can have a longitudinal axis and can be symmetrical or asymmetrical about this axis. The diameter of the chamber preferably decreases from the first end to the second end. In other embodiments, it can be envisaged that the chamber might increase in diameter from the first end to the second end or may be of a constant diameter along all or a portion of its length. Where the diameter of the chamber decreases in diameter away from the first end, the chamber can decrease in diameter relatively rapidly adjacent its first end and then decrease in diameter relatively slowly distal the first end. In another embodiment, the diameter can decrease relatively rapidly adjacent the first end and then remain at a constant diameter distal the first end. In a still further embodiment, the wall of the chamber can be substantially frusto-conical along at least a portion of its length.

The chamber can include at least one lug adapted to be connected to a belt, strap or other means of holding the chamber to the body of the user. In a preferred embodiment, the chamber has two oppositely disposed lugs at or adjacent its first end to which the respective ends of a belt are attached. In use, the belt is passed around the abdomen and is preferably adjustable or sufficiently elastic to hold the chamber in place against the body of the user.

pressure between about 1 and 5psi. The pumping means can include a pressure release valve that is set to limit the fluid pressure in the irrigating means.

The pumping means can include a fluid meter that measures the quantity of fluid that has passed through the catheter lumen and allows this measurement to be read by the user. The fluid meter can also, if desired, provide a signal to shutdown or otherwise regulate operation of the pumping means once a predetermined quantity of fluid has passed through the catheter lumen. When used to pump fluid into a stoma of the large intestine, the pump may pump between about 1 and 1.5 litres of fluid through the irrigating means. The total quantity of fluid will be dependent on the length of large intestine of the ostomate and the needs of the ostomate. For example, on a particular day, less fluid may be required than on another day.

Where water is used, the water can be supplied from any normal water source, including a mains tap or a portable water container. Where warm water is unavailable and if desired by the user, a heating means can be employed to warm the water before it is pumped through the catheter lumen. Such a heating means can comprise an electrical heating element that is placed in the water container before the water is drawn from the container by the pumping means.

In a further embodiment, the catheter can have an orifice engaging member that is engagable with the wall of the orifice in the mammalian body when the catheter is in the second position relative to the chamber. In one embodiment, the orifice engaging member is an expandable member positioned adjacent its free end that can be expanded when the catheter is in the second position within the bodily orifice. The expandable member can comprise a balloon member that is inflatable by passing a fluid through the catheter to expand the balloon member. In a preferred embodiment, the balloon member is in fluid communication with a separate lumen within the catheter. When a small quantity of air or another fluid is injected into the separate lumen, the balloon member is caused to expand. When the air or other fluid is extracted, the balloon member deflates. The balloon is preferably expandable such that it substantially seals with the wall of the bodily orifice. In a preferred embodiment, the expansion of the balloon member occludes the bodily orifice about the catheter. The expansion of the

the device to be positioned within bodily orifices of varying diameters. The sleeve can be formed from a silicone material.

The combination of the jaw member, when in the expanded condition, and the sleeve preferably defines a tubular area that extends outwardly from within the bodily orifice and is in fluid communication with the interior of the chamber.

The present device and system can be used to evacuate waste product through any suitable bodily orifice. It does, however, have particular application in the evacuation of waste product from natural and artificial stomas and, more particularly, colostomies.

According to a third aspect, the present invention consists in a device for evacuating waste product through an orifice in a mammalian body, the device including a chamber having an inlet and an outlet, the inlet being able to be brought into abutment with the body about the orifice and the outlet being connectable to a suction means, and an orifice engaging means that is insertable within the bodily orifice when the inlet of the chamber is in abutment with the body.

According to a fourth aspect, the present invention consists in a system for evacuating waste product through an orifice in a mammalian body, the system including a chamber having an inlet and an outlet, the inlet being able to be brought into abutment with the body about the orifice, a suction means that is connectable to the outlet and which can draw waste product at least from the chamber through the outlet, and an orifice engaging means that is insertable within the bodily orifice when the inlet of the chamber is in abutment with the body.

In one embodiment of the third or fourth aspects, the orifice engaging means is expandable from a collapsed condition to an expanded condition. When in the collapsed condition, the orifice engaging means is insertable within the bodily orifice. When in the expanded condition, the engaging means, when in the bodily orifice, preferably engages with the wall of the bodily orifice.

The engaging means can comprise an articulated jaw member that can be readily adjusted from the collapsed condition to the expanded condition and back to the collapsed condition. The jaw member can be encased within a non-rigid and preferably substantially cylindrical sleeve that is movable into abutment with the wall of the bodily orifice on articulation of the jaw

open. The valve is preferably readily manually operable by the user of the device but could be adapted to open automatically at regular or irregular intervals.

In one embodiment of the third and fourth aspects, the inlet of the chamber can seal with the body about the orifice. The inlet can be formed from a resiliently flexible material to assist this sealing. For example, the inlet can be formed from a polymeric or elastomeric material. In another embodiment, the inlet can be substantially circular, however, other inlet shapes can be readily envisaged. The inlet of the chamber can include a bellow means that allows the inlet to deform on abutment with the body. In one embodiment, the bellows can be formed of a silicone material. The inlet is preferably located at a first end of the chamber.

The outlet of the chamber in the third and fourth aspects is preferably located in a second end of the chamber distal the first end. The outlet preferably comprises an opening in the second end of the chamber. The opening is preferably surrounded by a spout extending outwardly from the second end and having a central bore in fluid communication with the opening. The spout preferably has an outer wall that tapers in diameter away from the second end. The spout is preferably detachably attachable to a pipe or tube that extends to or passes through a suction means. The tube or pipe preferably has a connector that allows relatively quick attachment of the tube or pipe to the spout by a user.

The second end of the chamber in the third and fourth aspects can be formed integrally with the chamber. In another embodiment, the second end can be formed separately and then mounted to the chamber. In one embodiment, the second end can have a skirt portion having a screw thread adapted to engage with a complementary screw thread on the container. The screw thread on the skirt portion can be on an inner or outer surface of the skirt portion, with the complementary screw thread on the outer or inner surface of the chamber, respectively. An O-ring can be located adjacent the screw thread between the skirt portion and the chamber to prevent waste product escaping from the chamber between the skirt portion and the wall of the chamber.

The second end of the device in the third and fourth aspects can be formed from a material different to that of the chamber. As an example only, the second end can be formed from a polymeric material, such as nylon.

The device and system of the third and fourth aspects, respectively, can be used to evacuate waste product through any suitable bodily orifice. It does, however, have particular application in the evacuation of waste product from artificial stomas and, more particularly, colostomies. The device can also be used to draw waste from the anus in the case where the user is suffering from chronic constipation. In this case, the device might be mounted in an appropriate way to a modified toilet seat to allow the user to sit comfortably on the toilet before using the device. The outlet of the suction means in this case could direct the waste product directly into the toilet bowl before the toilet is flushed in the usual manner.

In the above aspects, the device and/or system can comprise a portable device. Where a powered pumping means and/or suction means are utilised, the power for these devices can be provided by a battery. The battery is preferably rechargeable and portable along with the device. The device along with at least its pumping means, suction means and power source can preferably be carried in a case.

According to a further aspect, the present invention comprises a toilet having a seat, the seat having mounted thereto the device according to the third aspect of the present invention.

According to a still further aspect, the present invention comprises a toilet incorporating the system according to the fourth aspect of the present invention.

In a particularly preferred embodiment of all of the above aspects, the suction means and irrigating fluid pumping means used in association with the waste evacuator devices defined herein comprise the same device, collectively defined hereafter as "the pump". In the device and system of the third and fourth aspects, respectively, the pump in this case serves to force fluid into the irrigating means of the device and also provides the necessary suction to the outlet of the chamber. In the device and system of the second and third aspects, respectively, the pump serves to force fluid into the chamber through the fluid inlet and also provides the suction to the outlet of the chamber.

In one embodiment, the pump can comprise a dual-action peristaltic type pump. In such a pump, the pipe connecting an irrigating fluid source to the irrigating means or fluid inlet and the pipe connecting the outlet of the chamber to a waste collection means each pass through a housing of the

(iii) irrigating the bodily orifice with an irrigating fluid transported through the irrigating means; and

(iv) applying suction to the outlet of the chamber to withdraw waste from the orifice into the chamber and through the outlet.

In a preferred embodiment, the method includes after step (ii) an additional step of engaging the free end of the irrigating means with the bodily orifice prior to and preferably at all times while the bodily orifice is irrigated with the irrigating fluid. The additional step can further include forming a sealing engagement between the free end of the irrigating means and the wall of the bodily orifice. By sealing the orifice around the irrigating means, the irrigating fluid that enters the bodily orifice is retained within the bodily orifice until such time as the seal is removed. The sealing engagement of the free end can be provided by an inflatable balloon that occludes the orifice around the irrigating means. The irrigating means can be sealingly engaged with the wall of the bodily orifice for a period of time between about a few minutes and about a few hours, more preferably between about 5 minutes and about 2 hours, still more preferably between about 10 and about 30 minutes.

In the above aspect, suction can be applied to the second end of the chamber either after the step of irrigating the bodily orifice has commenced or is completed or before, during and after the step of irrigating the bodily orifice. Optimal functioning of the present invention may be different for each user depending upon comfort, physiology and experience, with steps (ii), (iii) and (iv) being utilised in different sequences and for different lengths of time by different users and by the same user but at different times.

While suction is being applied to the second end of the chamber, the further pressure equalisation orifice in the chamber is normally sealed by the user by placing a finger over the further orifice. As soon as the finger is removed from the further orifice, the air pressure in the chamber is equalised with that outside the chamber. The pressure equalisation orifice thereby provides a ready means for the user to control the degree of suction applied to the chamber.

This method has particular application to the evacuation of waste product from artificial stomas, such as colostomies. The method can, however, also be utilised to gently evacuate waste product from natural

This method has particular application to the evacuation of waste product from artificial stomas, such as colostomies. The method can, however, also be utilised to gently evacuate waste product from natural stomas, such as the anus. In a preferred embodiment, the method of using the defined system is operable by the user without assistance.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of one embodiment of the invention with the irrigating catheter shown in a first position;

Figure 2 is a perspective view of the embodiment of the invention depicted in Figure 1 but with the irrigating catheter shown in a second position;

Figure 3 is a perspective view of a second embodiment of the invention with the irrigating catheter shown in a first position;

Figure 4 is a perspective view of the embodiment of the invention depicted in Figure 3 but with the irrigating catheter shown in a second position;

Figure 5 is a perspective view of a third embodiment of the invention;

Figure 6 is a further perspective view of the embodiment of the invention depicted in Figure 5;

Figure 7 is a perspective view of a fourth embodiment of the invention;

Figure 8 is a side elevational view of a dual-action peristaltic pump for use in the present invention;

Figure 9 is a cross-sectional view of the pump of Figure 8 viewed along line I-I;

Figure 10 is a cross-sectional view of the pump of Figure 8 viewed along line II-II;

Figure 11 illustrates one use of one embodiment of the device according to the present invention;

Figure 12 illustrates use of a further embodiment of the device according to the invention.

Figure 13 depicts a plan view of a single-action peristaltic pump, with its cover removed, that can be used to draw waste product from the device according to the present invention;

of the user. It is envisaged that the free end 17 will extend relative to the inlet 14 a distance similar to that depicted in Figure 2. The other end 20 of the irrigating tube 16 is connected to the water source and, once free end 17 is in place within the intestine, water is forced at a suitable pressure through the irrigating tube 16. The water is expelled from irrigating tube 16 through an aperture 19 or a series of apertures located at free end 17 and into the intestine. Typically, around 1-2 litres of water can be introduced into the intestine in this way. It is envisaged that in a preferred embodiment of the invention, the water is not introduced in one step. A user may introduce a preliminary volume of water, say, 0.5 litres at first instance and add the remaining volume of water at varying time intervals thereafter. In this embodiment, the introduction of the preliminary volume of water has the advantage of stimulating the intestine to contract thereby aiding the natural process of evacuation of waste from the intestine. Once the required volume of water has been introduced into the intestine, the irrigating tube 16 is retracted from the intestine of the user and into the main chamber 11, as depicted in Figure 1.

As mentioned above, the water introduced into the intestine of the user stimulates a reflex contractile response in the intestine in addition to the process of irrigation which causes the water and any waste material in the intestine of the user to be dispelled. The water and waste material pass down through the intestine to the location of the orifice, through the orifice and into the main chamber 11 of device 10 . Once the waste is in the main chamber 11, it flows towards second end 13 and ultimately is drawn through outlet 15 via funnel 18 due to the suction provided by the suction pump. During this process, it may assist a user to continue to force water through irrigating tube 16 when it is retracted into the main chamber. In this way the continuing flow of water acts in a flushing manner further facilitating removal of the waste material from main chamber 11.

In another embodiment of the invention, depicted in Figures 3 and 4, the irrigating tube 16 is provided with a spacing cup 21 adjacent free end 17. In Figure 4, for the purposes of clarity, the spacing cup 21 is depicted as extending outwardly of inlet 14 but in actual use is more in alignment with inlet 14 such that it abuts with the skin surrounding an orifice, such as a colostomy. The spacing cup 21 may be attached to or integral with the irrigating tube 16 and is preferably made from a resiliently flexible polymeric

excessive loss of water from the orifice in addition to preventing relative movement of the irrigating tube 16 to the orifice.

In this embodiment the inlet 14 is again placed against the skin of the user about the stoma or other bodily orifice and air drawn out of the main chamber 11 through a funnel 18 attached to or integral with outlet 15. Once a small quantity of air is evacuated from the main chamber 11, the inlet 14 forms a suction seal with the skin surrounding the orifice of the user. When the inlet 14 is brought into sealing contact with the skin of a user, the irrigating tube 16 is moved into the bodily orifice such that it is positioned internal the intestine of the user. Once free end 17 is *in situ* within the intestine, the balloon 22, which is also positioned internal the intestine, is inflated such that it forms a seal around the bodily orifice. Water may then be introduced into the intestine through the irrigating tube 16 via aperture 19 or a series of apertures located at free end 17. The inflation of balloon 22 around the bodily orifice prevents any unnecessary leakage of water from the irrigating tube 16 at this stage.

In another embodiment of the invention depicted in Figure 7, the device 10 again comprises a main chamber 11 having two ends 12 and 13. An inlet 14 is located at end 12 and an outlet 15 positioned at end 13. A valve 24 is positioned about midway along the main chamber 11 such that the main chamber 11 is dividable into two separate compartments, first compartment 25 and second compartment 26. Extending from the first compartment 25 is an articulated jaw 27 which in use can be adjusted from a collapsed position to an expanded position (shown in phantom). In use, the device 10 is placed against the skin of a user and the inlet 14 caused to form a seal around the orifice of the user. The articulated jaw 27 extends into the orifice in its collapsed position and is subsequently adjusted to its expanded position. In its expanded position, the articulated jaw 27 engages with the wall of the intestine thereby preventing any leakage of waste material from the intestine. Preferably the articulated jaw 27 is encased within a substantially cylindrical and non-rigid sleeve such that when the articulated jaw is in an expanded position, the sleeve forms a tubular area which engages with the wall of the intestine of a user. The articulated jaw may be moved from a first collapsed position to a second expanded position by way of, for example, an adjusting device 30 connected to the articulated jaw 27 through a wall of main chamber 11.

preliminary volume of water stimulates the intestine to commence evacuation of waste material. Further volumes of water may then be introduced into the intestine at varying time intervals to irrigate the intestine and to remove further waste material. In this way, removal of waste is facilitated both by the natural movements of the intestine as well as by irrigation of the bowel. Additional suction will, of course, further facilitate removal of waste material from the intestine.

In a further embodiment of the invention as depicted in Figures 8 to 12, device 10 may be connected to a dual-action peristaltic pump 40. The pump 40 comprises a housing 41 and a motor 42. The pump 40 further comprises one or more rollers 48 mounted on a disc 49 adapted to rotate within the housing 41. The rotation of the disc 49 is provided by a central drive shaft 43 which is rotated by motor 42. The motor 42 can be mains powered or powered by a battery. Located on a side of the housing 41 is an inlet (a) and an outlet (b). In a preferred embodiment, inlet (a) and outlet (b) are simply slots in the side of the housing 41. Tubing 44 is connected to a water source and is adapted to pass through inlet (a), around the housing 41, between the rollers 48 and the wall of the housing 41, and out through outlet (b). As tubing 44 leaves the housing 41 through outlet (b) it connects with or is preferably integral with tubing 20 which in turn connects with the irrigating tube 16 of device 10.

Similarly, tubing 45 extends from funnel 18 of device 10 and carries waste material from the intestine through inlet (a) of housing 41. The tubing 45 is disposed immediately below tubing 44 in the housing 41. Again tubing 45 is adapted to pass through inlet (a), around the housing 41, between the rollers 48 and the wall of the housing 41, and out through outlet (b) where it is connected to or preferably integral with tubing 46 which transports the waste matter to a suitable receptacle such as a toilet.

In use, motor 42 causes rotation of the central drive shaft 43 which in turn causes rotation of disc 49. On rotation of disc 49, the rollers 48 compress tubes 44 and 45 against the wall of the main body 41. Any contents of the tubes 44 and 45 will therefore be squeezed through the tubes from inlet (a) to outlet (b). Accordingly, the water content of tubing 44 is squeezed through the pump 40 and ultimately into device 10 via tube 20. Similarly, the waste matter content of tubing 45 is passed through funnel 18

these components of the systems according to the present invention. For example, manually and mechanically operable piston-type and impeller-type pumps could be utilised as suction means to draw waste product from the chamber. Individual peristaltic pumps could also be utilised to both force irrigating fluid through the irrigating means and draw waste product from at least the chamber.

Whichever type of pump is utilised in association with the device or in the systems defined herein, the pump will operate to provide suction within medically approved ranges. The housing and componentry of the pumps can be constructed of any suitable material, such as polytetrafluoroethylene (PTFE).

While a dual action peristaltic pump as described above is preferred, other pump means can be utilised in association the device according to the present invention. For example, a single action peristaltic pump 50 can be utilised to draw waste through and from the main chamber 11 of device 10. An example of the type of peristaltic pump is shown in Figure 13, in which the waste product to be transported away from the main chamber 11 is forced by rollers 51, which rotate on the arms 52, through the flexible tubing 45, as the rollers 51 force the tubing 45 against the wall of the pump as they rotate around the pump. This embodiment has the advantage in that the waste product being evacuated is separated from the rotor of the pump, and that the tubing 45 can easily be cleaned by flushing or easily and cheaply replaced.

Other non-peristaltic type pumps can be utilised to draw waste products from the main chamber 11 of device 10. One example is the battery operated pump 53 shown in Figures 14 to 16. The pump 53 comprises a hand held body 54, having an inlet 55 with a non return inlet valve 56a of any suitable type, and an outlet 57 with a non return discharge valve 56b of any suitable type. Both the inlet 55 and the outlet 57 are in communication with the cylinder chamber 58. A drive piston 59 is slidably mounted in the cylinder chamber 58, and forms a labyrinth seal with the cylinder wall. A connecting rod 60 is pivotally connected, at one end, to the piston 59 and at the other end to a fly wheel 61. The fly wheel 61 is connected via a gear box 62 to an electric motor 63, which is powered by the battery 64.

To use the pump 53, a user first connects the inlet 55 of the pump 53 into sealing engagement with the tubing 45 extending from outlet 18 of the chamber 11, and operates the switch 65. The piston 59 reciprocates along

engagement with the wall of the circular cavity 84. The pump 80 is controlled by a bi-directional motor 89, with a forward or reverse switch 90.

To use the pump 80, a user firstly places the inlet/outlet 82 of the pump 80 into sealing engagement with the tubing 45 extending from funnel 18 of the main chamber 11 and operates the switch 90 drawing waste product from the main chamber 11 by rotating impeller 87 and discharging it through the outlet/inlet 83. The pumping is continued until sufficient waste has been evacuated from the main chamber 11. If desired, such a pump 80 can also be used to pump water or a stool softening fluid through the irrigating catheter 16 and into the bodily orifice.

A potentiometer can be located on the pumps described herein to vary the speed of the motor and hence the suction head. The pumps are so designed to operate within medically approved pressure ranges. Preferably the pumps are waterproof and can be constructed of any suitable material, such as polytetrafluoroethylene (PTFE).

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty third day of June 1999

COLOCARE HOLDINGS PTY LIMITED
Patent Attorneys for the Applicant:

F B RICE & CO

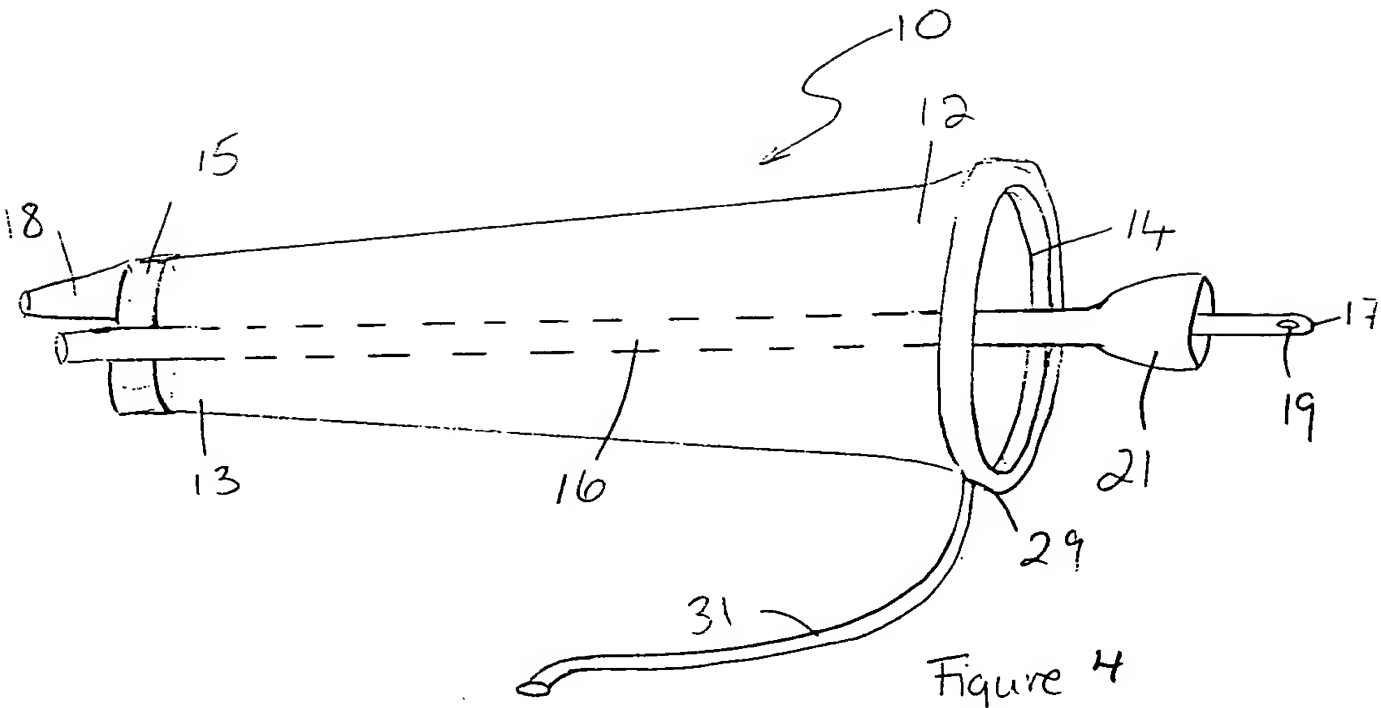

Figure 4

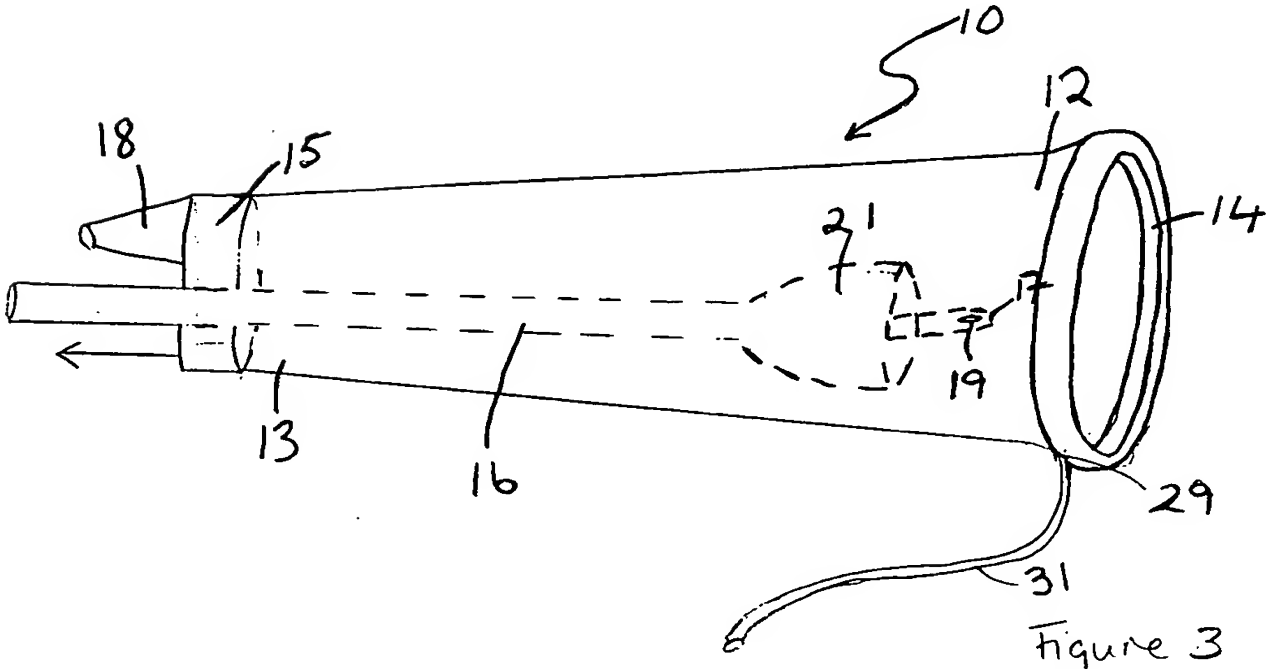

Figure 3

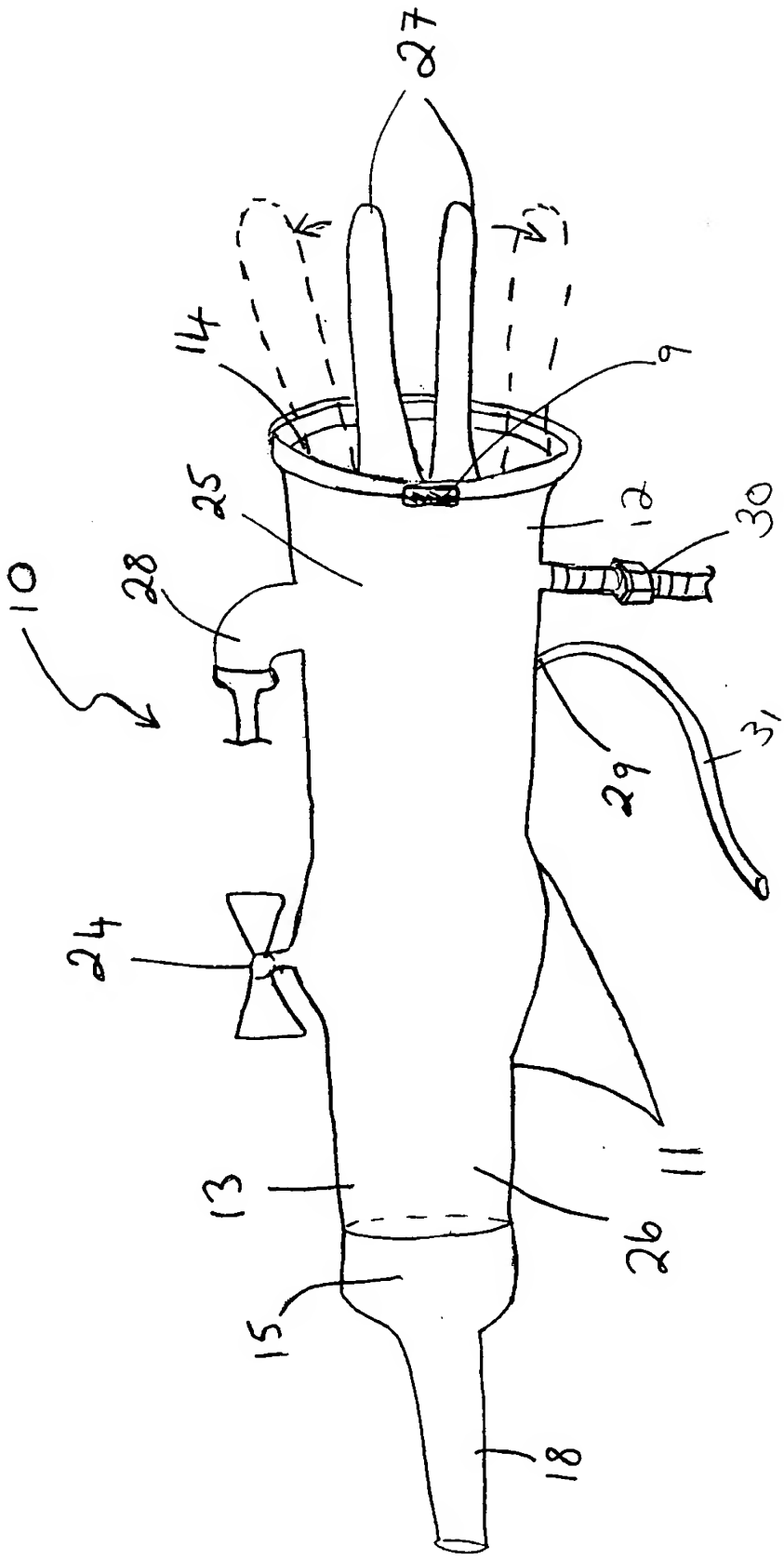

Figure 7

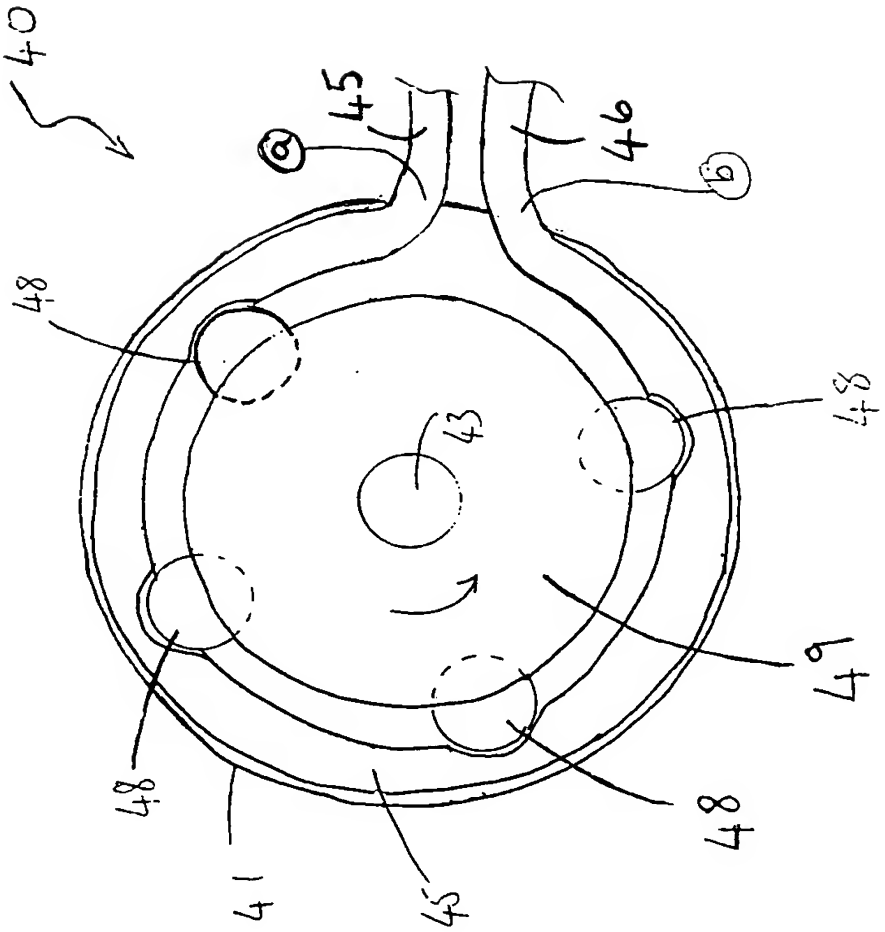

Figure 10

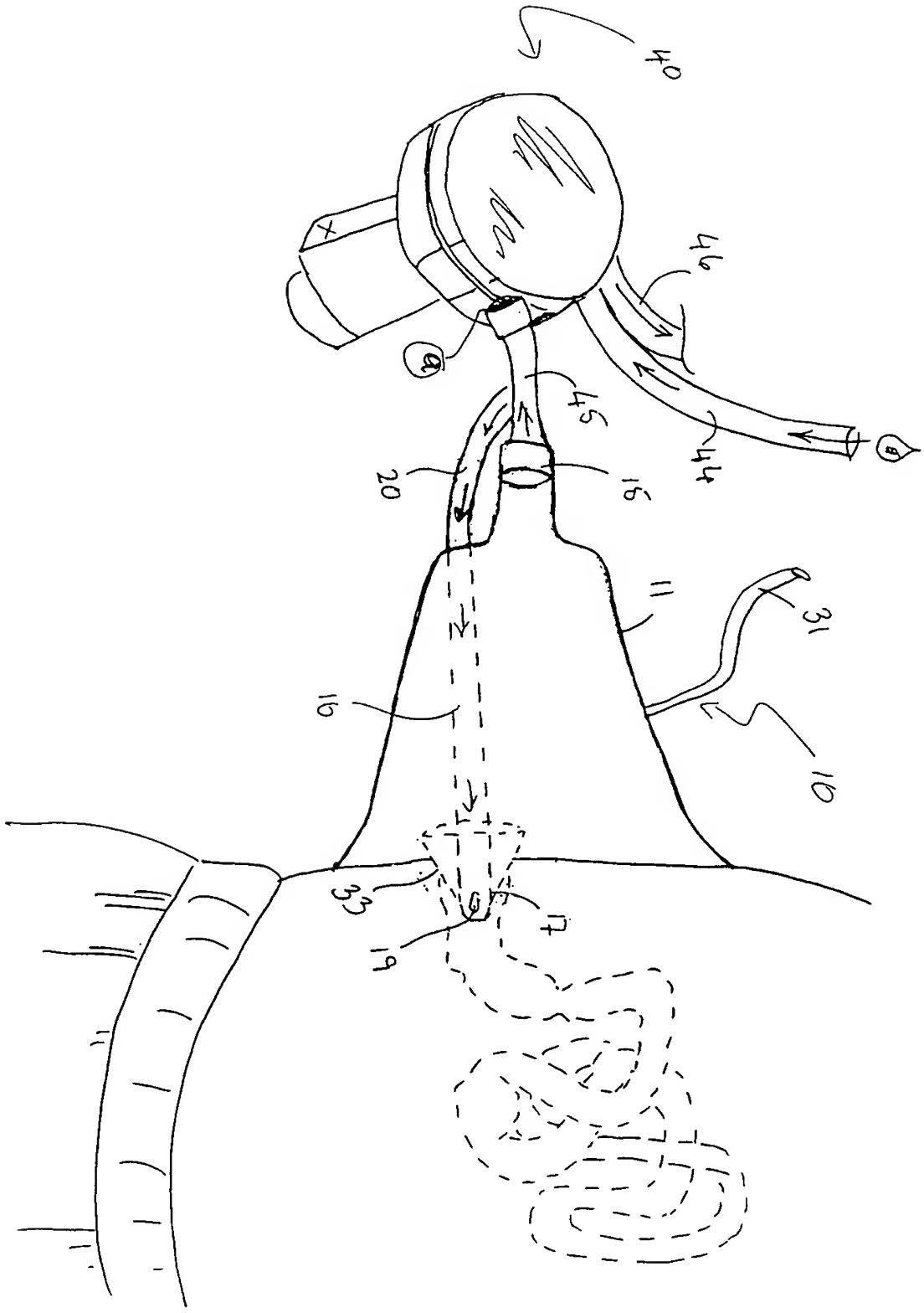

Figure 12

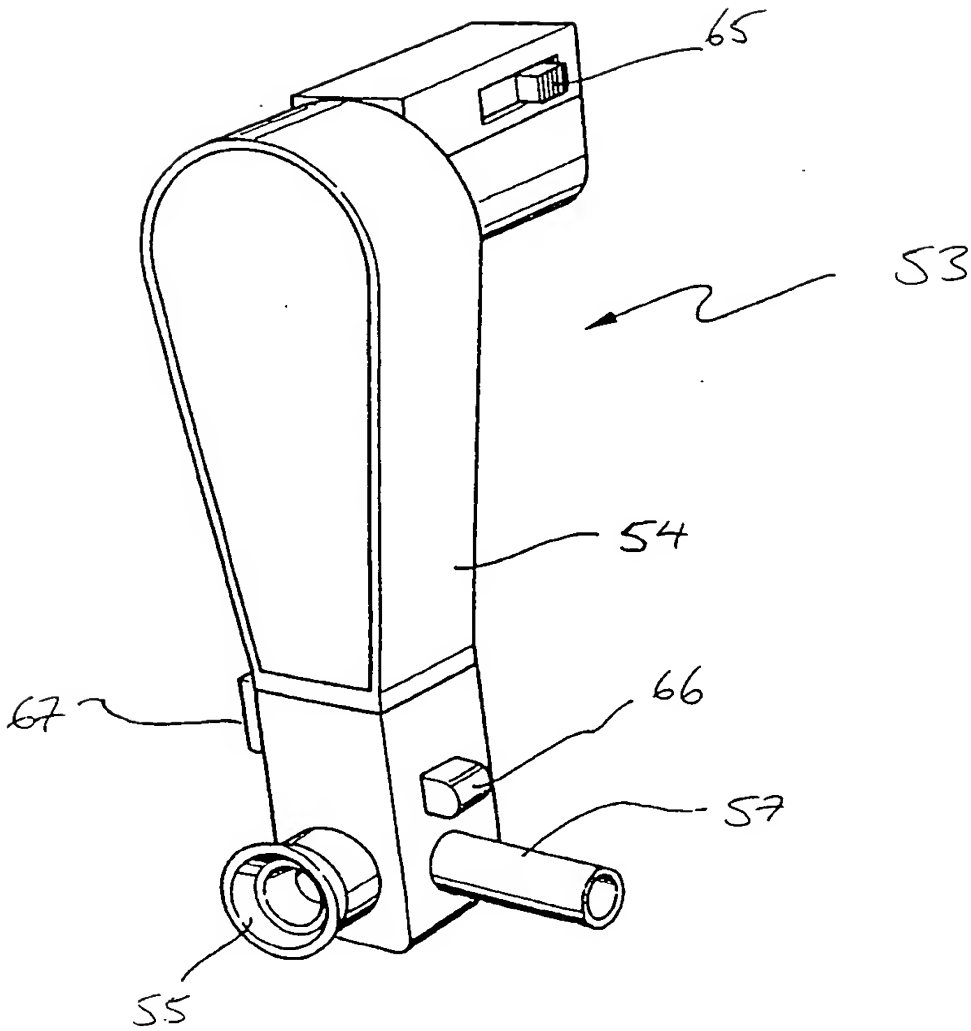

FIG. 14

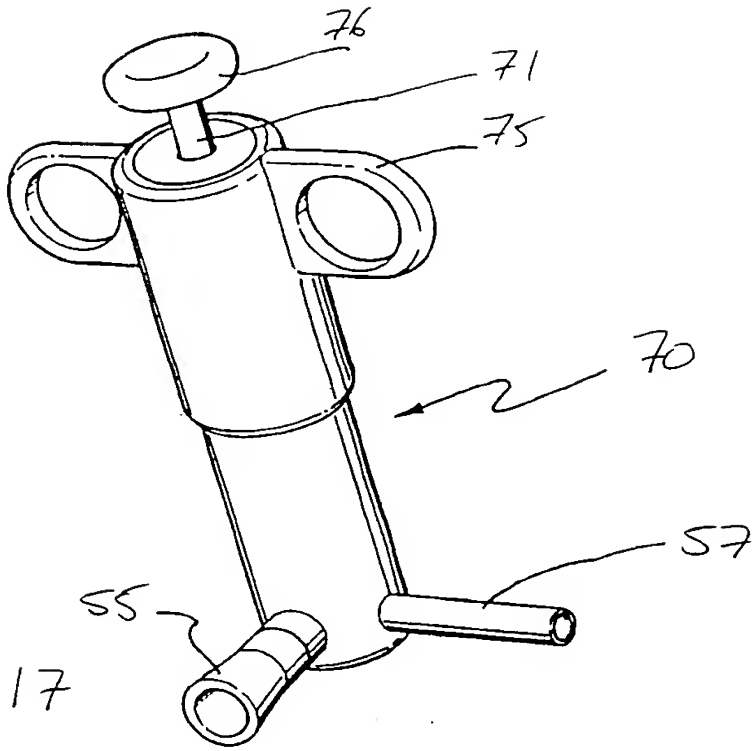

FIG. 17

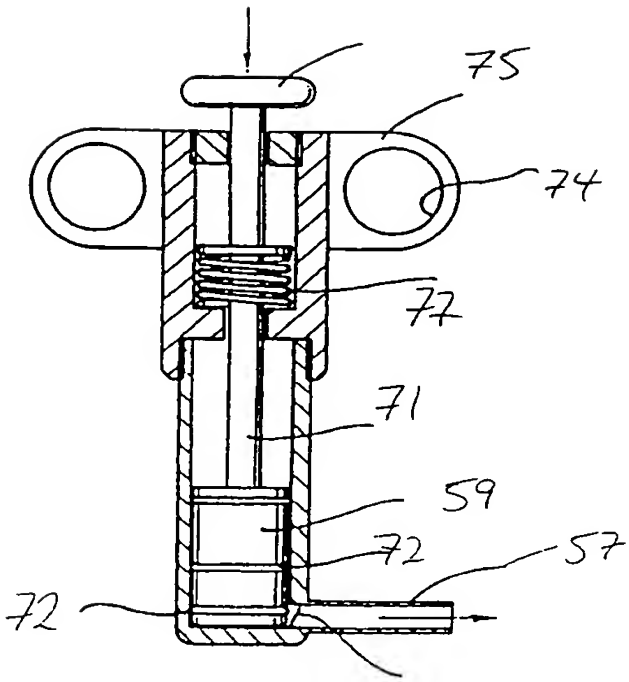

FIG. 18

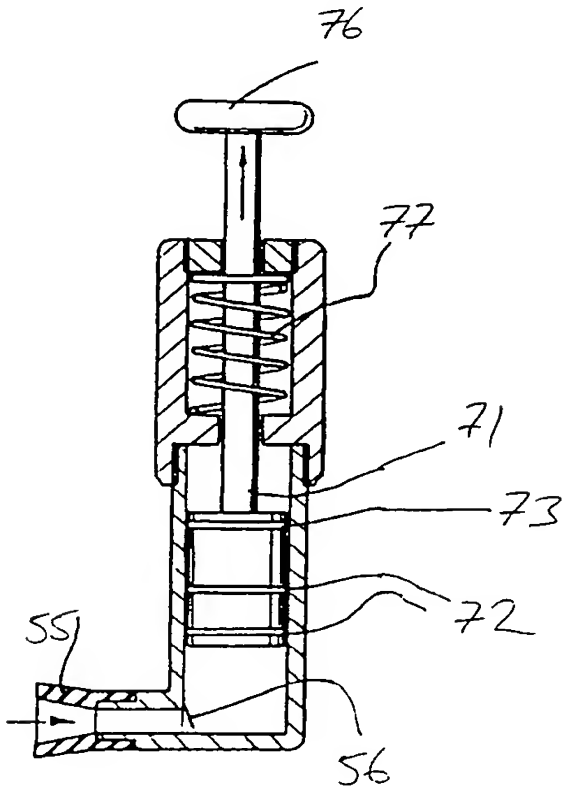

FIG. 19